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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,404	07/16/2003	James M. Ntambi	960296.99128	2922

7590 11/27/2006

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EXAMINER	
SCHLIENTZ, NATHAN W	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,404	NTAMBI ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 12 and 13 are withdrawn from consideration as they are drawn to a non-elected invention.

2. Please not that "thiazoladinedione" as in claim 4 is understood by the examiner to be "thiazolidinedione".

3. No claim is allowed at this time.

Response to Remarks Filed on 27 October 2006

4. In an office action mailed on 25 August 2006, examiner restricted between two groups of inventions. Group I, claims 1-11, is drawn to a method of increasing insulin sensitivity, and Group II, claims 12 and 13, is drawn to a method of identifying an agent that can increase insulin sensitivity. Applicant's arguments filed 27 October 2006 have been fully considered but they are not found persuasive. Applicant's argument that the invention of Group II is related to the invention of Group I, in that they are capable of use together is not found persuasive. The invention of Group II potentially involves libraries of species that are screened for a particular property; however, the libraries cannot be used in conjunction with the invention of Group I. The invention of Group I can only be used with the particular species deemed efficacious towards increasing insulin sensitivity. Also, the invention of Group II is conducted *in vitro*, whereas, the invention of Group I is conducted *in vivo*, and they are therefore not capable of use together.

5. Applicant's argument that the invention of Group I and II have similar effects in that they both end in an increase in insulin sensitivity is also not found persuasive. The invention of Group II is a method of screening libraries of compounds, the majority of which will most likely not result in an increase in insulin sensitivity. The invention of Group I is an *in vivo* method of increasing insulin sensitivity where the drug has been proven to increase insulin sensitivity in the subject.

6. Applicant's argument that the inventions of Groups I and II can be searched together without serious burden is also not found persuasive. The two inventions require different classification searches and therefore require undue burden on the examiner.

7. For the reasons stated in the office action sent on 25 August 2006, the restriction requirement is made **FINAL**.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-5 and 7-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 -9 of copending Application No. 10/094,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is drawn to a method of increasing insulin sensitivity in a human or non-human subject through reducing stearoyl-CoA desaturase 1 (SCD1) activity by inhibiting the enzymatic activity of SCD1. The claims of application '841 are drawn toward a method of controlling body fat in a human or non-human subject through reducing SCD1 activity by inhibiting the enzymatic activity of SCD1. The two methods comprise identical steps, and therefore the resulting effect is inherent in the method. Therefore, the instant claims are obvious over the claims of '841.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1, 8 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 48 of copending Application No. 11/195,561. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of increasing insulin sensitivity in a human or non-human subject by inhibiting the enzymatic activity of SCD1 through administering an SCD1 inhibitor. Claim 48 of

application '561 is drawn to a method for treating diabetes and insulin resistance in an individual comprising the step of administering to that individual an inhibitor of an SCD1 protein expression or activity. Both applications are drawn to administering an inhibitor of SCD1 activity for the purpose of treating insulin resistance/increasing insulin sensitivity. Therefore the instant claims are obvious over claim 48 of '561.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

13. The instant claims are drawn to a method of increasing insulin sensitivity in a human or non-human subject by reducing SCD1 activity in the subject through administering an antisense oligonucleotide for SCD1 or an SCD1 inhibitor such as an SCD1 antibody or by inhbiting cytochrome b_5, NADH-cytochrome b_5 reductase, or terminal cyanide-sensitive desaturase. The specification discusses in great detail

various assays that could be used to identify potential compounds that reduce SCD1 activity, but does not provide guidance as to which compounds should be screened. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work. The applicant states, "virtually any number of chemical extracts or compounds can be screened using the exemplary methods described". "Examples of such extracts or compounds include... plant-, fungal-, prokaryotic-, or animal-based extracts, fermentation broths, and synthetic compounds, as well as modification of existing compounds" (see page 21, paragraph 83). The applicant further states that "the agent(s) contemplated by the present disclosure includes agents of any size or chemical character, either large or small molecules, including proteins, such as antibodies, nucleic acids, either RNA or DNA, and small chemical structures, such as small organic molecules" (see specification page 22, paragraph 85). However, the specification does not direct a person skilled in the art which compounds have the desired characteristic of reducing SCD1 activity. See *Univeristy of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (W.D.N.Y. 2003). Therefore, the instant claims and the specification contain no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention.

14. Claims 1 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

15. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention
2) the state of the prior art
3) the relative skill of those in the art
4) the predictability of the art
5) the breadth of the claims
6) the amount of direction or guidance provided
7) the presence or absence of working examples
8) the quantity of experimentation necessary

16. The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention

17. The claimed invention relates to a method of increasing insulin sensitivity in a human or non-human subject by reducing SCD1 activity in the subject. Reduced SCD1 activity in the subject is claimed to result from reduced SCD1 protein level by administering an antisense oligonucleotide for SCD1, inhibition of SCD1 enzymatic activity by administering an SCD1 antibody, as well as inhibition of cytochrome b_5, NADH-cytochrome b_5 reductase, or terminal cyanide-sensitive desaturase.

The state of the prior art

18. SCD1 is well known in the art as a microsomal enzyme that catalyzes the synthesis of monounsaturated fatty acids by introducing the cis double bond in the delta-9 position of palmitoyl-CoA and stearoyl-CoA. These monounsaturated fatty acids are used as substrates for the synthesis of triglycerides, wax esters, cholesteryl esters and membrane phospholipids.

The predictability of the art

19. Methods of reducing enzymatic activity *in vivo* are very difficult to predict. Multiple screening methods are employed to determine which compounds from a library of possibilities have the desired reduction of enzymatic activity *in vitro*. The compounds are then screened for efficacy *in vivo*, without undesired side effects. Therefore, considerable experimentation is required to determine an agents efficacy toward a defined enzymatic activity in a desired host.

The breadth of the claims

20. The instant claims are very broad. The claims are drawn to a method of increasing insulin sensitivity by administering an antisense oligonucleotide, an inhibitor of SCD1 such as an SCD1 antibody, or an inhibitor of cytochrome b_5, NADH-cytochrome b_5 reductase, or terminal cyanide-sensitive desaturase. The term antisense oligonucleotide is generic and encompasses a number of oligonucleotides of varying lengths and sequence. Similarly, an SCD1 antibody encompasses any antibody that is specific to SCD1. Lastly, an inhibitor of cytochrome b_5, NADH-cytochrome b_5

reductase, or terminal cyanide-sensitive desaturase can encompass a plethora of species.

The amount of direction or guidance provided

21. The specification does not provide a person of ordinary skill in the art with sufficient direction or guidance to practice the claimed invention. The specification does describe how to conduct assays "for identifying agents that inhibit SCD1 expression or enzymatic activity" (see specification pages 10 and 11, paragraph 38). The specification also describes how to deliver the compounds identified from the aforementioned assays (pages 22 and 23, paragraphs 89 and 90). However, there is no guidance as to how to determine which compounds to screen with the expectation of success.

The quantity of experimentation necessary

22. To practice the claimed invention, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success. The invention essentially calls for the use of trial and error to attempt to find a compound that will increasing insulin sensitivity in a human or non-human subject by reducing SCD1 activity in the subject. As disclosed by the applicant, "virtually any number of chemical extracts or compounds can be screened using the exemplary methods described". "Examples of such extracts or compounds include... plant-, fungal-, prokaryotic-, or animal-based extracts, fermentation broths, and synthetic compounds, as well as modification of existing compounds" (see page 21, paragraph 83). The applicant further states that "the agent(s) contemplated by the present disclosure includes agents of any

size or chemical character, either large or small molecules, including proteins, such as antibodies, nucleic acids, either RNA or DNA, and small chemical structures, such as small organic molecules" (see specification page 22, paragraph 85). Therefore, undue experimentation on the part of one skilled in the art would be required to determine which compounds to screen with an expectation of success.

23. Therefore, for the aforementioned reasons, the applicant is not enabled for increasing insulin sensitivity through administering an antisense oligonucleotide for SCD1, an SCD1 antibody, or an inhibitor of cytochrome b_5, NADH-cytochrome b_5 reductase, or terminal cyanide-sensitive desaturase.

24. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for BRL49653, pioglitazone, ciglitazone, englitazone, and troglitazone, does not reasonably provide enablement for thiazolidinedione compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

25. Attention is again directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation.

26. The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention

27. The claimed invention relates to a method of increasing insulin sensitivity in a human or non-human subject by reducing SCD1 activity in the subject. Reduced SCD1 activity in the subject is claimed to result from reduced SCD1 protein level by inhibiting SCD1 gene transcription through administering a thiazolidinedione compound or a polysaturated fatty acid.

The state of the prior art

28. SCD1 is well known in the art as a microsomal enzyme that catalyzes the synthesis of monounsaturated fatty acids by introducing the cis double bond in the delta-9 position of palmitoyl-CoA and stearoyl-CoA. These monounsaturated fatty acids are used as substrates for the synthesis of triglycerides, wax esters, cholesteryl esters and membrane phospholipids.

The breadth of the claims

29. The instant claims are very broad. The claims are directed to a method of administering a thiazolidinedione compound or a polysaturated fatty acid. A thiazolidinedione compound is any compound that has a thiazolidin-2,4-dione ring structure as part of the molecule, and therefore encompasses a vast number of possible species. Likewise, a polysaturated fatty acid is any compound that contains a polysaturated lipid-carboxylic acid chain, and therefore also encompasses a vast number of possible species.

The amount of direction or guidance provided

30. The applicant does not provide any direction or guidance with respect to determining which species are defined by the terms thiazolidinedione compound and polysaturated fatty acid. The specification does list some thiazolidinedione compounds, such as BRL49653, pioglitazone, ciglitazone, englitazone, and troglitazone. However, the instant claims are in no way limited to these examples. Unfortunately, the specification does not provide any examples of polysaturated fatty acids, nor any guidance to determine which species are incorporated in its definition.

The quantity of experimentation necessary

31. To practice the claimed invention, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success. The instant claims are drawn to numerous species, of which determining the efficacy would require extensive experimental experimentation.

32. Therefore, for the aforementioned reasons, the applicant, while being enable for BRL49653, pioglitazone, ciglitazone, englitazone, and troglitazone, does not reasonably provide enablement for administering an agent selected from a thiazolidinedione compound and a polysaturated fatty acid.

33. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

34. The instant claim is drawn to a method of increasing insulin sensitivity by inhibiting cytochrome b_5, NADH-cytochrome b_5 reductase or terminal cyanide-sensitive desaturase. However, the specification does not teach a person skilled in the art how to inhibit any of the above-mentioned proteins, nor does the specification teach whether an inhibitor of these proteins would increase insulin sensitivity in the subject. The specification states SCD activity depends upon the formation of a stable complex between the three components (page 10, paragraph 36), but the specification does not teach one skilled in the art how to determine what compounds are effective inhibitors of the above-mentioned proteins. The specification also fails to show that inhibition of one of the said proteins will reduce SCD1 and lead to increased insulin sensitivity.

35. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Administering a **polysaturated** fatty acid to increase insulin sensitivity, as in claim 4, is not disclosed in the specification. The specification does however disclose **polyunsaturated** fatty acids as transcription inhibitory agents to inhibit the synthesis of SCD1 protein (specification page 8, paragraph 28). Therefore, one of ordinary skill in the art would not be able to reproduce the invention as disclosed in claim 4.

36. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

37. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

38. The recitation of "reducing SCD1 activity... **sufficiently** to increase insulin sensitivity" in claim 1 is not clearly defined by the claims or the specification. It is unclear as to what extent the SCD1 activity must be reduced to be sufficient to increase insulin sensitivity. The claim implies that there is a lower limit to reducing SCD1 activity that is necessary in order to increase insulin sensitivity. However, the specification merely recites a necessity for the level of SCD1 activity in a human or non-human subject be lowered (page 7, paragraph 24). The specification does not address to what extent the SCD1 activity must be reduced to achieve an increase in insulin sensitivity. Therefore, in light of the specification, the recitation reducing SCD1 activity sufficiently to increase insulin sensitivity in claim 1 is indefinite.

39. Claims 1-3, 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to lack of an active ingredient or an active step. See MPEP § 2172.01. The instant claims fail to set forth an active ingredient and an active step for achieving the desired purpose.

40. The instant claims are drawn to a method of increasing insulin sensitivity in a human or non-human subject by reducing SCD1 activity in the subject. However, the instant claims fail to provide an active ingredient and an active step that performs said

method. The instant claims do no more than describe the desired function of the compound called for, and contain no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention.

41. Claim 6 recites the limitation "polyunsaturated fatty acid" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 6 is dependent from claim 4, which recites the limitation polysaturated fatty acid.

42. Claim 7 recites the limitation "SCD1 protein level is reduced" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 7 is dependent from claim 1, which recites "reducing SCD1 activity", but does not limit this reduction in activity to a reduction in SCD1 protein level.

43. Claim 11 recites the limitation "the inhibitor" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 11 is dependent from claim 8, which recites "reducing SCD1 activity is accomplished by inhibiting the enzymatic activity of SCD1", but does not recite the use of an inhibitor, as is seen in claim 9.

Claim Rejections - 35 USC § 102

44. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

45. Claims 1-5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehmann et al. (J. Biol. Chem., 1995).

46. The instant claims are drawn to a method of increasing insulin activity in a human or non-human by administering a thiazolidinedione compound selected from the group consisting of BRL49653, pioglitazone, ciglitazone, englitazone and troglitazone. Lehmann et al. teach thiazolidinedione derivatives are antidiabetic agents that increase the insulin sensitivity of target tissues in animal models (abstract and page 12953, right column, lines 29-32). Lehmann et al. further teach the thiazolidinedione compounds BRL49653, pioglitazone, ciglitazone, and englitazone fall within a class of structurally related antidiabetic agents (page 12954, left column, lines 66-68, and Fig. 1C). Through administering the thiazolidinedione compounds in an effort to treat diabetes, Lehmann et al. are inherently increasing insulin sensitivity by inhibiting the transcription of the SCD1 gene, and Lehmann et al. are also inherently inhibiting the protein cytochrome b_5, NADH-cytochrome b_5 reductase, or terminal cyanide-sensitive desaturase. Therefore, for the foregoing reasons, Lehmann et al. anticipate all the limitations of the instant claims.

47. Claims 1-4, 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ntambi et al. (Biochemical and Biophysical Research Communications, 1996).

48. The instant claims are drawn to a method of increasing insulin activity in a human or non-human by administering a polyunsaturated fatty acid selected from the group consisting of dodecahexaenoic acid and arachidonic acid. Ntambi et al. teach the insulin-stimulated expression of SCD1 mRNA was significantly blunted when the induction medium was supplemented with linolenic acid and arachidonic acid (abstract). Ntambi et al. further teach supplementing with linolenic acid and arachidonic acid repressed induction of SCD1 mRNA by 85% and >90% respectively (page 992, lines 10-11 of the first full paragraph). Ntambi et al. have shown that polyunsaturated fatty acids, including arachidonic acid, inhibit SCD1 gene transcription (page 991, lines 9-11). Because Ntambi et al. have shown arachidonic acid inhibits SCD1 gene transcription, arachidonic acid inherently increases insulin sensitivity. Through inhibiting the transcription of the SCD1 gene with linolenic acid or arachidonic acid, Ntambi et al. are inherently inhibiting the protein cytochrome b_5, NADH-cytochrome b_5 reductase, or terminal cyanide-sensitive desaturase. Therefore, for the foregoing reasons, Ntambi et al. anticipate all the limitations of the instant claims.

49. Claims 1, 7 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Crooke et al. (US 7,132,529).

50. The instant claims are drawn to a method of increasing insulin sensitivity through administering an antisense oligonucleotide for SCD1. Crooke et al. disclose a method of inhibiting the expression of human SCD comprising contacting the cells or tissues in vitro with an antisense oligonucleotide (claim 10). Crooke et al. further disclose antisense oligonucleotides as capable of modulating the expression of SCD (col. 3,

lines 24-39), which has been implicated in various diseases including diabetes (col. 2, lines 1-5). As a result of the antisense oligonucleotide of Crooke et al. inhibiting the expression of SCD, the antisense oligonucleotide inherently increases insulin sensitivity by reducing SCD protein level. Through inhibiting the expression of SCD1 with an antisense oligonucleotide, Crooke et al. are inherently inhibiting the protein cytochrome b_5, NADH-cytochrome b_5 reductase, or terminal cyanide-sensitive desaturase. Therefore, for the foregoing reasons, Crooke et al. anticipate all the limitations of the instant claims.

51. Claims 1-5, 7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Ntambi et al. (US 2003/0064950 A1).

52. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

53. The instant claims are drawn toward a method of increasing insulin sensitivity in a human or non-human subject through reducing SCD1 activity (claim 1), which is accomplished by administering a thiazolidinedione compound or a polysaturated fatty acid, an antisense oligonucleotide, or an antibody. Ntambi et al. disclose a method for controlling body fat in a human or non-human subject through reducing SCD1 activity, wherein reducing SCD1 activity is accomplished by administering a thiazolidinedione

compound or a polysaturated fatty acid (claim 4), an antisense oligonucleotide (claim 6), or an antibody (claim 9). The steps in the method are identical with the instant claims, except, the intended result is different. However, in an attempt to control body fat through reducing SCD1 activity, one is inherently increasingly insulin sensitivity in the subject. Therefore, for the foregoing reasons, Ntambi et al. anticipate all the limitations of the instant claims.

54. Claims 1 and 8-11 rejected under 35 U.S.C. 102(e) as being anticipated by Hayden et al. (US 2003/0157552 A1).

55. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

56. The instant claims are drawn to a method of increasing insulin sensitivity through administering an SCD1 antibody. Hayden et al. disclose a method of treating diabetes or insulin resistance through administering an inhibitor of an SCD1 protein expression or activity (claim 48). Through treating insulin resistance, Hayden et al. are increasing insulin sensitivity. Also, through inhibiting SCD1 protein activity, Hayden et al. are inherently inhibiting one of the proteins cytochrome b_5, NADH-cytochrome b_5 reductase, or terminal cyanide-sensitive desaturase. Therefore, for the foregoing reasons, Hayden et al. anticipate all the limitations of the instant claims.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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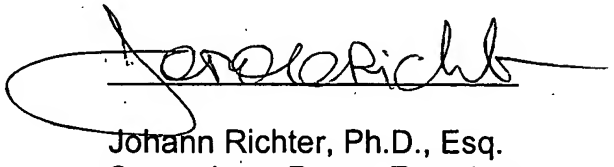

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